CASE BT/3-22349/A/PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF
STUART GREENHALGH ET AL.
INTERNATIONAL APPLICATION NO. PCT/EP 04/013250
FILED: November 22, 2004
FOR: PROCESS OF PRODUCING POLYMERS
U.S. APPLICATION NO: 10/580,447
35 USC 371 DATE: MAY 23, 2006

Group Art Unit: 1651
Examiner: Sheridan R. Macauley

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This Appeal is from the Final Rejection mailed from the PTO on December 11, 2009.

A Notice of Appeal was filed electronically on March 9th, 2010.

Filing of this Appeal Brief is timely up to and including May 9, 2010. The Brief is accompanied by the requisite fee under 41.20.

The Commissioner is authorized to charge any fee due, or credit any overcharge, as a result of this Amendment to Deposit Account No. 03-1935.

(1) REAL PARTY OF INTEREST

The real party of interest, by virtue of an assignment recorded in the United States Patent and Trademark Office on June 7, 2007 reel/frame 019423/0418 is:

Ciba Specialty Chemicals Water Treatments Ltd
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(2) RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any related appeals and interferences for the above application.

(3) STATUS OF THE CLAIMS

Claim 13 is cancelled.
Claims 1-12 and 14-18 are pending.

(4) STATUS OF AMENDMENTS

The claims were last amended on August 7, 2009. As no amendments were filed after Final, the claims are as last amended on August 7, 2009.

This brings up to date the status of the claims. A clean copy of the claims is attached in the (8) Claims Appendix.

(5) SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 1 is the only independent claim and is directed to a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtained from a biocatalysed reaction or a fermentation process. The monomer must contain cellular material and/or components of a fermentation broth. The process further includes the forming of the polymer by polymerizing the

ethylenically unsaturated monomer or a monomer mixture comprising the ethylennically unsaturated monomer and cellular material and/or components of a fermentation broth in the presence of a redox and/or thermal initiator and the formed polymer exhibits an intrinsic viscosity of at least 3 dl/g measured using a suspended level viscometer in 1 M sodium chloride at 25 °C.

Basis for the above claim can be found on page 7, lines 19 through the end of the page and onto page 8. lines 1-4.

The presence of a redox and/or thermal initiator, is supported by the disclosure on page 14, lines 17-18. The viscosity of the formed polymer is defined on page 13, lines 9-13.

It is generally expected that the presence of either the biocatalyst or the fermentation broth would have a detrimental effect on the polymerization and the final polymer product that is formed. However, contrary to these expectations polymerizing the monomer in the presence of the biocatalyst or the fermentation broth results in the desired polymers without any impairment. This statement is supported by the disclosure on page 8, lines 27-30 continuing through the top of page 9, through line 5.

While it is known that acrylamide monomer may be produced by a biocatalytic route, it is generally accepted that even small quantities of impurities can affect the polymerization of monomers or prevent polymerization taking place at all. For instance initiating systems used for polymerization are used in tiny amounts and therefore it would require only small amounts of impurities to inactivate them, stopping or short-stopping the polymerization. Such impurities may result in branching, cross-linking, chain termination or other effects on the polymer. See disclosure page 4, lines 16-22.

But most importantly, the examples (see Table 2 and 3 on page 19) show that when the acrylamide is formed via fermentation and when both the centrifuged and non-centrifuged acrylmide samples are polymerized as homo-polymers using redox and thermal inititators to give gel polymers, virtually no differences are observed in the samples prepared using both centrifuged and uncentrifuged acrylamide. Furthermore, the flocculant properties of the two gel polymers preformed similarily.

Thus the present process allows for substantially no removal of cellular material and or components of the fermentation broth from the ethlenically unsaturated monomer. The avoidance of this purification is although deceptively simply, one not envisioned or considered previously.

As all the other claims ultimately depend from claim 1, each requires the presence of cellular material and /or components of a fermentation broth and subsequent polymerization without removal of the cellular material and/or components of fermentation.

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-12 and 14-18 are rejected under 35 USC 103(a) as obvious over Yamada, US 5,334,519 in view of Seki, US 5,352,828 and Leonova, Biotechnology, 1000, 88:231-241.

(7) ARGUMENTS

The Appeal will stand or fall on the basis of claim 1.

The present claim limitations require that the monomer is obtained from a biocatalyzed reaction or a fermentation process, and the monomer contains cellular material and/or components of a fermentation broth, and the polymer is formed by polymerizing the monomer in the presence of cellular material and/or components of a fermentation broth in the presence of initiators and the formed polymer exhibits an intrinsic viscosity of at least 3 dl/g.

Examiner states that in the process of Yamada after the substrate is converted into a monomer, it contains cellular material and/or components. However, Yamada separates the monomer from cellular and/or components of fermentation before polymerization.

Examiner agrees with the Appellants that Yamada does not teach the formation of a polymer in the vessel comprising the ethylenically unsaturated monomer wherein the unsaturated monomer comprises cellular material and/or components of the fermentation broth.

However, Seki teaches that solutions of acrylamide will occur under most conditions, such as in the presence of iron. Thus according to the Examiner it is either inherent to the teachings of Yamada, or polymerization would occur during routine optimization and experimentation. Appellants submit that one skilled in the art needs to consider Yamada as it is. Not as the examiner speculates it might be.

In fact, Yamada teaches that **No** polymerization takes place as the monomer is produced in 100% yield (example 4). One skilled in the must take Yamada as it explicitly teaches.

The use of Seki's teachings by examiner that polymerization was **likely** to occur in a concentrated monomer mixture and thus **could** have occurred in the highly concentrated monomer mixture of Yamada as it contained debris from the fermentation process is at a minimum speculative and ignores the teachings of Yamada as a whole.

Seki teaches in col. 1, lines 34 to 45 of Seki:

> "that microbiological methods, on the other hand, have no impurities such as metal ions as a matter of course, and the amount of by-products is markedly small in comparison with the copper catalyst process (for producing acrylamide) because the enzyme reaction is effected under ordinary temperature and pressure, thus rendering possible simplification of a refining step or even its omission. However, when a high performance polymer is produced for use in the aforementioned coagulating agent and the like, **it is necessary to increase the purity of acrylamide as much as possible.**"

Examiner stated in his rejection, page 8 under "Response to Arguments"

> ."., Seki teaches that the claimed polymer is popcorn-like (co. 5, lines 14-21); it therefore appears that the polymer, once separated from the mixture, would exhibit a solidity that would place it within the claimed viscosity range."

The example of "popcorn formation" referred to by the examiner in Seki (col. 5, lines 14-21) is one in which the pure **acrylamide (separated from the cellular components)** is **purposely** exposed to an iron surface at 50 °C.

Appellants point out that popcorn-polymer is an **abnormal reaction encountered in free-radical polymerization systems**. The popcorn-polymer has a popcorn- (hence the name) or cauliflower-like shape, and a white, opaque appearance that is easily distinguished from clear polymer obtained from normal polymerization.

Popcorn polymer does not swell in solvents. Thus the examiner's statement that "the polymer, once separated from the mixture, would exhibit a solidity that would place it within the claimed viscosity range" is indeed speculative.

As explained in the present disclosure it is generally accepted that elimination of the purification step (removal of cellular material and/or fermentation broth) would not work because the presence of even small quantities of impurities would affect the polymerization. Seki confirms this view in col. 1, lines 34-45.

As discusses in the present disclosure on page 4, lines 11-24:

> "It is standard practice to remove the biocatalytic cells from the growth medium before using the biomass to produce the monomers in order to avoid contamination of the monomer by impurities that could adversely affect the successful polymerization of the monomer. It is generally accepted that even small quantities of impurities can affect the polymerization of monomers or prevent polymerization taking place at all. For instance initiating systems used for polymerization are used in tiny amounts and therefore it would require only small amounts of impurities to inactivate them, stopping or short-stopping the polymerization. Such impurities may result in branching , cross-linking, chain termination or other effects on the polymer."

The surprising aspect of the present invention is the fact that polymerization occurs without adverse effects on the polymer per se even in the presence of cellular and/or fermentation broth. This is clearly shown in the comparisons run in the examples wherein a polymer formed from a monomer formed by biocatalysis which is not separated from its fermentation broth performs as well as that which is centrifuged from fermentation broth. See Tables 2 and 3 on page 19.

Thus the Appellants are the first to understand that the removal of the cellular material and/or components of a fermentation broth need not take place before polymerization. The formed polymer performs as well as the monomer subjected to the purification step.

The Examiner has failed to consider the invention as a whole. That is the process of the invention eliminates a purification step, previously considered necessary. The result is a product of surprising viscosity and performance.

The issue here is not whether polymerization might have occurred or might not have occurred in the experimentation of Yamada (and Yamada **specifically states it did not occur**, while the Examiner believes that because of the teachings of Seki it was likely to occur). The Appellants submit this is pure speculation on the part of the Examiner.

The problem with the Examiner's rejection is he has given an obviousness rejection based on inherency. If an obviousness rejection is based on inherency, the unexpected property of the present

process (production of flocculants of relatively high viscosity which perform well without the purification step) could only inhere in a post-invention rationalization, which is at most a possibility and not a proper basis for obviousness.

Further the examiner has failed to consider the invention as a whole. Yamada never suggested the polymerization of the monomer formed by biocatalysis without a purification step. Examiner believes the experimentation run in Yamada would have **likely** resulted in polymerization because of the statements of Seki. However, Yamada states **no** polymerization took place. Selective teachings of Seki bring into question whether polymerization would have occurred during microbiological production as postulated by the Examiner. Seki teaches that these microbiological methods have no impurities such as metal ions as a matter of course. See col.1, lines 34-35. Then the Examiner takes an example from Seki showing polymerization of monomer when deliberately exposed to an iron surface and uses this as justification for his opinion that polymerization would inherently occur in the methods of Yamada.

But the fact is the presently claimed process eliminates the necessity of a pre-separation step, which no one skilled in the art recognized could have been eliminated and still achieve a product of high quality (high viscosity and good performance as a flocculant).

Even if polymerization might occur in the experiments of Yamada (and Appellants believe this to not be the case because Yamada states **no** polymerization took place), this spontaneous polymerization would not lead to a polymer of the desired quality. See col. 5, lines 14-21 of Seki where a popcorn-like polymer is produced.

The Examiner has mentioned in his advisory action of April 2, 2010 that the "applicant argues that the claimed invention provides the surprising result that polymerization may occur in unpurified media, it is noted that this feature was known in the art, as taught by Seki." The Appellants bring to the Boards attention that while it is known that impurities may cause polymerization of acrylamide for example, as taught by Seki, the important point missed by the Examiner is the Appellants are not claiming a method in **any** unpurified media but in a **media containing cellular material and/or components of a fermentation broth**.

To summarize:

- Examiner's rejection is based on Yamada and Seki. Yamada teaches a process for the biological production of an ethylenically unsaturated amide.
- Examiner agrees that Yamada does NOT teach polymerization of the unsaturated amide in the presence of cellular material and/or components of a fermentation broth.
- Thus Examiner supplies Seki which teaches that acrylamide MAY polymerize in the presence of impurities.
- Examiner believes that since Seki teaches that impurities are likely to cause spontaneous polymerization of acrylamide, polymerization would have occurred in Yamada during routine experimentation (even though Yamada teaches no polymerization occurred).
- Seki does not make any statements which would lead one skilled in art to believe that acrylamide could be polymerized successfully in the presence of cellular material and/or components of a fermentation broth. In fact, he teaches the reverse. See col. 1, lines 41-44 wherein Seki teaches that when a high performance polymer is produced for use in the aforementioned coagulating agent and the like, it is necessary to **increase the purity** of acrylamide as much as possible.
- The fact remains that Yamada teaches that NO polymerization occurs and Seki absolutely believes that purity is important to achieving adequately performing polymers. Not the popcorn polymer formation when impurities are not controlled in example2, col. 5, lines 20-21.
- Appellants believe the Examiner's statement that such polymerization is likely to occur (or inherent) during experimentation is pure speculation. And the use of Seki is misplaced and missing the vital point that the present claim limitations are directed to a method of preparing a polymer in the presence of cellular material and/or or components of a fermentation broth.
- In order to judge the obviousness of the claimed method one must look to the references and what they teach as a whole. Yamada teaches NO polymerization of ethylenically unsaturated monomers in the presence of cellular material and/or components of a fermentation broth. Yamada teaches separation from the broth or cellular material before polymerization takes place. Seki teaches that in order to form a high performance polymer it is necessary to **increase the purity** of acrylamide as much as possible.
- Thus, the combination by the Examiner fails to consider the references as they actually are and teach as a whole. In reading both references one skilled in the art would not arrive at the method as presently claimed.

In light of the above discussions, Appellants respectfully submit that the rejections of claims 1-12 and 14-18 have been rebutted and respectfully ask that the rejections be reconsidered and reversed.

Respectfully submitted,

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(8) CLAIMS APPENDIX

1. (previously presented): A process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtained from a biocatalysed reaction or a fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation broth, forming the polymer by polymerising the ethylenically unsaturated monomer or a monomer mixture comprising the ethylenically unsaturated monomer and cellular material and/or components of a fermentation broth in the presence of a redox and/or thermal initiator and the formed polymer exhibits an intrinsic viscosity of at least 3 dl/g measured using a suspended level viscometer in 1 M sodium chloride at 25 °C.

2. (previously presented): A process according to claim 1 in which the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into the ethylenically unsaturated monomer,
contacting the substrate with a biocatalyst which biocatalyst comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and/or components of a fermentation broth and this process is carried out inside or outside of the cell and where it is carried out inside the cell it optionally forms part of a metabolic pathway of the microorganism.

3.(original): A process according to claim 2 in which the biocatalyst comprises a microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism.

4. (previously presented):A process according to claim 1 in which the cellular material comprises whole cells.

5. (previously presented):A process according to claim 1 in which the cellular material comprises fractured cellular material.

6. (original): A process according to claim 5 in which the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell nucleus material, cytoplasm and proteins.

7. (previously presented): A process according to claim 1 in which the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators,enzyme inducers and complex fermentation medium components.

8. (previously presented): A process according to claim 1 in which the ethylenically unsaturated monomer is (meth)acrylamide monomer.

9. (previously presented): A process according to claim 2 in which the substrate is (meth)acrylonitrile.

10. (previously presented): A process according to claim 2 in which the biocatalyst comprises a nitrile hydratase enzyme.

11. (previously presented): A process according to claim 1 in which the polymer is a homopolymer or copolymer of (meth) acrylamide.

12. (previously presented): A process according to claim 1 in which the ethylenically unsaturated monomer is selected from the group consisting of itaconic acid (or salts thereof), maleic acid (or salts thereof) and (meth) acrylic acid (or salts or derivatives thereof).

13. (cancelled).

14. (previously presented): A process according to claim 2 in which the substrate is introduced into a vessel and contacted with a biocatalyst and wherein the substrate is converted into the ethylenically unsaturated monomer,

optionally introducing other monomers into the vessel to form a monomer mixture,

subjecting the ethylenically unsaturated monomer or monomer mixture to polymerisation conditions, optionally by introducing initiators into the vessel,

and

thereby forming the polymer inside the vessel.

15. (original): A process according to claim 14 in which the biocatalyst is produced in the vessel.

16. (previously presented): A process according to claim 2 in which the biocatalyst comprises microorganisms of the Rhodococcus genus.

17. (original): A process according to claim 16 in which the microorganism is Rhodococcus rhodochrous NCIMB 41164.

18. (previously presented): A composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or components of a fermentation broth, wherein the composition is obtained by a process according to claim 1.

(9) EVIDENCE APPENDIX

No additional evidence is supplied to support this Appeal.

(10) RELATED PROCEEDINGS APPENDIX

As the appellants are not aware of any other related proceedings, no copies of decisions rendered by a court or the board are attached.